

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Steven Brown on June 17, 2009.

In the claims:

Canceled non-elected claims 68-76.

2. An updated IDS dated 9/29/04 is attached that contains the dates for Muller and Roth references.

### **REASONS FOR ALLOWANCE**

3. The following is an examiner's statement of reasons for allowance: the instant claims define over the prior art of record, specifically Fitzpatrick et al because Fitzpatrick does not teach a device comprising a sample application zone having a labeled indicator reagent that does not bind to the analyte, a test zone having an immobilized, pre-determined amount of a first reagent that binds to both the labeled indicator reagent and to the analyte and produce a signal that is inversely proportional the analyte concentration, and a reference zone having a pre-determined amount of immobilized second reagent that binds to the labeled indicator reagent to produce a signal that is directly proportional to the analyte concentration. The detectable response in the test

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zone plus the detectable response in the reference zone equal a total detectable response that is substantially constant for the predetermined range of analyte concentration.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/

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Primary Examiner, Art Unit 1641

June 15, 2009